

HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, June 30, 2010

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

Agenda:

Wednesday, June 30, 2010

Time: 1:00-2:30 ET

Dial-in info: number 1-877-423-2663

PIN# 517342

- **Overview of Pillbox Initiative**

David Hale (NLM); Bill Hess (FDA); Teresa Watkins (FDA); Lonnie Smith (FDA)

Some background (from material provided by presenter):

The National Library of Medicine (NLM) and Food and Drug Administration (FDA) have established Pillbox, an initiative to enhance patient safety through the availability of digital images of solid oral dosage form medications (<http://pillbox.nlm.nih.gov>). The images would be provided by drug manufacturers and distributors in the Structured Product Labeling (SPL) files submitted to FDA. The NLM will use these images to create a search system allowing patients, healthcare providers and the public to identify medications. NLM is providing a free service to manufacturers and distributors to image solid oral dosage forms for inclusion in the SPL files. This document describes how to take advantage of this service.

Images that are currently available to the public from various online resources not related to SPL are of varying quality. There exists no single, authoritative resource of high-quality images representative of prescription and non-prescription medications available in the United States. The availability of such a resource and metadata quantifying the visual characteristics of each sample would provide opportunities for operationalization in areas such as poison control, emergency response, disaster response, anti-counterfeiting, manufacturer compliance with federal regulations, improved prescription filling accuracy, and reduction of adverse drug events. To address this issue, drug manufacturers and distributors may provide a standardized image of a solid oral dosage form to help describe the appearance of the drug with the SPL file submitted to the FDA as part of the drug listing process. This standardized image is linked to the SPLIMAGE data element in the SPL file. At this time, FDA only accepts images in SPLIMAGE generated by NLM using a defined standardized imaging process.

The National Library of Medicine, through the support of the Food and Drug Administration, has set up a photography laboratory in Rockville, MD for the purpose of generating standardized images of sample solid oral dosage forms. The images encompass visible spectrum only. Ultra-violet and infrared images will not be captured. No tests or assays of any nature are performed on the samples.

Currently, there are approximately 1000 samples – of generic solid dose products -- being photographed. The project is looking for (1) samples of innovator and generic products for both Rx and OTC solid dose forms; and (2) comments on the standard

Q: What if a company already has images of solid dosage products. Would you want to take the photos again?

A: We're looking to develop a standard to provide a common working method. To be able to provide a standard image (with regards to compression, other image standards)

Q: Is the standard available for comment now?

A: Document is still in draft. Target availability is late-August 2010.

Q: What identifying characteristics should be supplied with the samples?

A: Still working that out, and looking for input from sponsors. To complete DEA paperwork, and allow sample verification, basic information such as point of contact (e-mail, physical address, name) and ingredients, special handling instructions, NDC will be useful.

Q: What will you do with the samples first?

A: A Pharmacist will verify sample using identifying information to check against solid dose form itself.

Q: How will you store the samples if they require special handling?

A: The pharmacy is secure. The samples are stored in a double-walled safe. It is operating under a DEA license that requires documentation of materials upon arrival and audits of the process through to the destruction of the samples.

Q: What will you do with the samples after they have been photographed?

A: After the samples have been photographed, the samples will be destroyed. Documentation of the destruction of the samples, along with the solid dose form image, will be provided to the contact that supplied the samples.

- **New FDA-SRS UNII search web site** <http://fdasis.nlm.nih.gov>

Q: Will both the spreadsheet and the website be in use at the same time?

A: FDA will keep the spreadsheet active for a while. Right now, the website has a delay of approximately 1 – 2 days from the spreadsheet. The FDA will look into automating the process of the website updates.

Q: There have been reports of people having problems searching for a product by name or part of a name. They could find product by UNII code, though.

A: Please send examples to: FDA-SRS@fda.hhs.gov

- **Medication Guide validation file (to be on SPL data council website in near future):** additional validation files zip file.
FDA will be contacting firms that are missing MedGuide sections.
- **Federal register notice, Indexing SPL for Human Rx Drugs & Biologics; request for comments**
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM217297.pdf>
- **General Q&A**
Overall SPL submissions are going well, quality of files keeps getting better.
OTC Monograph product SPLs are coming in, as are a lot of Medical Gases SPL files.

FYI

- New validation rules – specific matches against business operations – will go into production in the next several weeks.
- Minutes of previous Process Team meetings are here:
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>

Next meeting scheduled for:

Wednesday, July 14, 2010

Time: 1:00-2:30 ET

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